

FEE TRANSMITTAL for FY 2007

Effective 2/8/2006. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 970

Complete if Known

Application Number 10/802,829
Filing Date August 3, 2004
First Named Inventor Dale J. Kempf
Examiner Name Raymond J. Henley III
Art Unit 1614
Attorney Docket No. 7050USO2

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None
Order

☒ Deposit Account:

Deposit
Account
Number

01-0025

Deposit
Account
Name

Abbott Laboratories

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1011	300	2011	150	Utility filing fee	
1012	200	2012	100	Design filing fee	
1013	200	2013	100	Plant filing fee	
1014	300	2014	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	
SUBTOTAL (1)					(\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
20 **	0	0	0
Independent Claims	3 **	0	0
Multiple Dependent			0

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	50	2202	25	Claims in excess of 20	
1201	200	2201	100	Independent claims in excess of 3	
1203	360	2203	180	Multiple dependent claim, if not paid	
1204	200	2204	100	** Reissue independent claims over original patent	
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive - unavoidable	
1453	1500	2453	750	Petition to revive - unintentional	
1462	400	1462	400	Petition fee under 37 CFR 1.17(f)	
1463	200	1463	200	Petition fee under 37 CFR 1.17(g)	
1464	130	1464	130	Petition fee under 37 CFR 1.17(h)	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	790

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 970

4. SEARCH/EXAMINATION FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1111	500	2111	250	Utility Search Fee	
1112	100	2112	50	Design Search Fee	
1113	300	2113	150	Plant Search Fee	
1114	500	2114	250	Reissue Search Fee	
1311	200	2311	100	Utility Examination Fee	
1312	130	2312	65	Design Examination Fee	
1313	160	2313	80	Plant Examination Fee	
1314	600	2314	300	Reissue Examination Fee	
SUBTOTAL (4)					(\$) 0

SUBMITTED BY

Name (Print/Type) Lydia N. Nengow Registration No. (Attorney/Agent) 52,530 Telephone (847) 938-0389
Signature [Signature] Date February 27, 2007



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/395,772	03/24/2003	Dale J. Kempf	7050.US.01	3797
23492	7590	06/01/2004	EXAMINER PESELEV, ELLI	
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/395,772

Applicant(s)

KEMPF ET AL.

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 118 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☐ Claim(s) 1-4, 7-9 and 12-18 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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The Agarwala et reference listed in the submitted IDS has not been received.

Claims 7, 8 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds listed in claim 9, does not reasonably provide enablement for an active pharmaceutical agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Since not all pharmaceutically active agents cause elevated serum concentration of an UGT1A1 substrate and since there is a large number of known pharmaceutical agents, it would take an undue amount of experimentation to determine which specific pharmaceutical agents will be useful in the claimed methods.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "consisting essentially of" (claim 9) is an improper Markush terminology. Such terminology as "consisting of" can be used to overcome the rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Norbeck et al (U.S. Patent No. 6,037,157).

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Norbeck et al disclose a method of administration of retonavir in a single or divided doses of from 0.001 to 300 mg/kg body weight daily (column 11, lines 65-68) and column 12, lines 1-4). The induced UGT1A1 isoform expression, increase of glucuronidation of an UGT1A1 substrate and increase of excretion of an UGR1A1 substrate would have been inherent in the reference's method.

Claims 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200